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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,898	08/22/2003	Joar Opheim	03-109	1343

23843 7590 05/23/2006
FOOTHILL LAW GROUP, LLP
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EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,898

Applicant(s)

OPHEIM, JOAR

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04/10/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's amendment, terminal disclaimers, and declaration, all filed 12/07/2005; and IDS filed 04/10/2006.

Claims 10-13 have been cancelled, claims 1-9 are pending and included in the prosecution.

Terminal Disclaimer

1. The terminal disclaimers filed on 04/10/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any of U.S. Patent No. 6,346,231, U.S. Patent No. 6,641,837, and U.S. Patent No. 6,652,879 have been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

Art Unit: 1615

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 as amended has introduced new matter because nowhere in the specification applicant has disclosed that the "flavoring agent dissolved in said gelatin capsule, softener and water". On page 5, lines 5-14, applicant disclosed that the "the manufacturing process includes the steps of combining gelswatch ingredients, melting and forming liquefied gelswatch". The specification has not support for "flavoring agent dissolved in the gelatin capsule, softener and water".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lachman et al. in combination with US 5,955,102 ('102).

Lachman teaches a capsule shell comprising gelatin, plasticizer, water and flavor. The amount of plasticizer is calculated to be 40-60% and chosen according to the end use of the capsule and the effect of capsulated material on the shell. The amount of water is calculated to be 70-130% but water is lost during drying process.

Art Unit: 1615

The flavor is present in a concentration of 0.1% to impart the desirable taste in chewable capsule (page 407, right column).

Lachman does not teach the claimed amount of the water and plasticizer, or fish oil as a dietary supplement.

However, Lachman suggested that plasticizer is chosen according to the end use of the capsule and the effect of capsulated material on the shell, and this teaching would have motivated one having ordinary skill in the art to adjust the amount of plasticizer according to the intended use and encapsulated material.

Additionally, Lachman teaches that the water is lost during drying process, i.e. the amount is expected to be radically reduced below 70%. Note that applicant discloses in page 6 of the specification, lines 1-2, that the amount of water present in the shell is 10-45%, and that amount is reduced to 8+/-2% after drying of the capsule. The reference does not disclose if the amount before drying or after drying.

In any event, the amount of water and plasticizer do not impart patentability to the claims, absent evidence to the contrary.

Fish oil is well known dietary supplement, and also known to be provided in a gelatin capsules.

US '102 teaches fish oil is preferably provided in a gelatin capsule (abstract; col.2, lines 31-36).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the gelatin capsule disclosed by Lachman that comprises gelatin, softener, water and small amount of flavor and use the capsule

Art Unit: 1615

to deliver fish oil disclosed by US '102, motivated by the teaching of US '102 that the gelatin capsules are the preferred delivery method for the fish oil, with reasonable expectation of having a gelatin capsule comprising shell containing 1% of flavoring agent to impart the desired taste as disclosed by Lachman to deliver fish oil to the patient in need with great success.

Response to Arguments

6. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

7. The declaration under 37 CFR 1.132 filed 04/10/2006 is insufficient to overcome the rejection of claim 1-10 based upon 35 U.S.C. 103 (a) as set forth in the last Office action because: It refers only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. The scope of the claims is broad covering all flavors in any amounts while the declaration is limited only to one flavor, i.e. Firmenich 52311A, at specific concentration 0.5 to 1.0% of the flavoring agent because applicant declares that below 0.5% flavoring agent gives distorted flavor and above 1.0 it gives harsh taste. The species of the flavoring agent in specific concentration in the shell composition of the declaration does not support the generic concept of the claims. In view of the foregoing,

Art Unit: 1615

when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

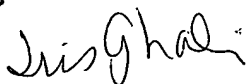
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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**ISIS GHALI
PATENT EXAMINER**